

**AMENDMENTS TO THE DRAWINGS:**

Please find accompanying this response a replacement sheet for Fig. 4, wherein amendments explained in the Remarks presented below are effected.

**REMARKS**

Claims 1-10 and 12-16 are now pending in this application. Claims 1-10 and 12-15 are rejected. Claim 11 is previously cancelled. Claims 1, 3, 9, 10, 14 and 15 are amended herein to clarify the invention, to express the invention in alternative wording and to address matters of form unrelated to substantive patentability issues. New claim 16 is added.

The applicants and applicants' attorney appreciate the Examiner's granting of the telephone interview conducted on January 8, 2009, and extend their thanks to the Examiner for her time and consideration. No agreement was reached, and the Examiner maintained her position stated in the final Office Action of August 28, 2008. However, the Examiner suggested that the claims, in the form as argued, did not relate the various cells to a centrifugal disk or disks on which they are arranged, and therefore should be rewritten to relate the cells within the context of the rotatable disk. The claims herein are amended on the basis of this recommendation, as discussed more fully below.

Applicants herein traverse and respectfully request reconsideration of the rejection of the claims and objection cited in the above-referenced Office Action.

The Examiner objects to the drawings under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims.

Regarding claim 7, a Replacement Sheet is provided herewith including Fig. 4, which is amended to include a schematic depiction of the motor recited therein. The description is also amended to reflect the revise figure. No new matter is added in making this drawing revision.

With regard to claim 10, the terms “flat face” and “step” are cancelled from the claims, rendering the objection to the drawings, based upon use of these terms, moot.

Applicants, however, traverse the drawing objections with regard to alleged lack of depiction of the term “shelf” recited in claim 10. The Examiner’s attention is drawn to Fig. 3, in which the shelf 9 is clearly depicted, and described, for example, at page 15, first full paragraph.

Regarding claim 14, the recitation of “motor for separation and motor for determination” has been removed from the claim.

Based upon the foregoing, withdrawal of the drawing objection is respectfully requested.

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter lacking an adequate written description in the specification. Applicants herein respectfully traverse this rejection.

Applicants believe the Examiner’s reference to the drawings as not being drawn to “scale” is misplaced, insofar as the claims do not recite anything which relates relative size of one element to another element. Thus, it is irrelevant whether

the drawings depict the invention in terms of “precise proportions” as averred by the Examiner.

Rather, claim 10 merely recites structure which fully coincides with that shown and described, and as including a shelf present at the boundary of the insoluble matter collection zone and the supernatant separation zone extending horizontally from a radially inward side surface of the insoluble matter collection zone towards the rotational center of the disk and which continues radially inward to a corresponding radially inward side surface of said supernatant separation zone. This recitation finds full support in the specification, and as clearly understood by one of ordinary skill in the art.

Therefore, in view of the above, reconsideration of the rejections of claim 10 is respectfully requested. Should such rejection be maintained, it is requested that the Examiner explain the grounds for the rejection, addressing the above remarks, to comply with satisfying the burden of the PTO in asserting the rejection. “The burden of showing that the claimed invention is *not* described in the application rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient.” *In re Edwards, Rice, and Soulen*, 196 U.S.P.Q. 465, 469 (CCPA 1978) *citing: In re Salem*, 553 F.2d 676, 682, 193 USPQ 513, 518 (CCPA 1977); *In re Wertheim*, 541 F.2d at 265, 191 USPQ at 98.

Claims 3, 10 and 14 are rejected as indefinite under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter

of the invention as a result of informalities stated in the Office Action. The claims are amended to remove or correct the informalities noted in the Office Action. Therefore, reconsideration of the rejection of claims 3, 10 and 14, and their allowance, are earnestly requested.

Claims 1-6 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson (US 3,586,484). Applicants herein respectfully traverse these rejections. "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). It is respectfully submitted that the cited reference is deficient with regard to the following.

Independent claim 1 recites in pertinent part the following:

a reaction disk body which is rotatable about a centrally disposed rotational axis running perpendicular to a horizontally disposed disk expanse; and

at least one separation cell and at least one determination cell being respectively arranged along a periphery of the reaction disk body located radially outward of said rotational axis, said at least one

separation cell and said at least one determination cell being provided as discrete cell units which are independently separate from one another in a same said reaction disk body, at least a radially outward internal wall of each of said at least one separation cell and said at least one determination cell being maintained in a substantially parallel orientation with respect to said rotational axis even during rotation of said reaction disk body, said at least one separation cell including a structural configuration for preventing a suspension from flowing out during centrifugal separation, supernatant separated by said centrifugal separation from the suspension contained in the separation cell being dispensable to the determination cell to allow analysis of a target substance in the supernatant

In its amended form above, claim 1 recites that at least a radially outward internal wall of each of at least one separation cell and at least one determination cell is maintained in a substantially parallel orientation with respect to a rotational axis of a reaction disk body containing the respective cells even during rotation of the

reaction disk body. Applicants respectfully submit that Anderson is devoid of such teaching. Rather, the interior walls of the chambers 12 are disclosed as being comprised of “a plurality . . . of sloping cylindrical cavities.” (Emphasis added). As such, the radially outward internal wall of the cavities (part of the cylinder facing radially outward) which are “sloping,” in a significant manner as to prevent loss of contents when rotated, cannot reasonably be said to be “maintained in a substantially parallel orientation with respect to said rotational axis,” as claimed.

Furthermore, applicants respectfully submit that Anderson fails to provide teaching directed to “at least one separation cell and said at least one determination cell being provided as discrete cell units which are independently separate from one another in a same said reaction disk body.”

The Examiner alleges in the Response to Arguments section of the final Office Action that “separation cells in transfer discs 11 and cuvettes 9 in the rotary cuvette ring 5 are ‘independently distinct and separate from one another’ in the same reaction disc 1. Applicants respectfully disagree. When assembled as a unified assembly (rotor assembly 1), “[a]n upwardly and outwardly extending passageway 17 leads from the base of each holding chamber 16 to the radially innermost part of a cuvette 9.” (Col. 2, lines 64-66). Thus, it is clear that the reaction cuvette 9 of Anderson, being equated by the Examiner with the claimed determination cell, is not a discrete cell independently separate from the separation cells. This fact is even admitted in the final Office Action at page 6, wherein it is stated that “Anderson also

teaches that the separated supernatant in the separation cell is dispensed to the determination cell (cuvette 9) through passageway 17 upon further rotation of the reaction disk.” (Emphasis added). Such interconnection is in direct contradiction to the claimed recitation requiring that the respective cells be separate and discrete.

In view of the above, it is respectfully submitted that claims 1-8 particularly describe and distinctly claim elements not disclosed in the cited reference. Therefore, reconsideration of the rejections of claims 1-6 and 15 and their allowance are respectfully requested.

Claims 1, 3-8 and 13-15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Guigan (US 5,077,013). Applicants herein respectfully traverse these rejections. It is respectfully submitted that the cited reference is deficient with regard to the following.

Independent claim 1 requires that at least one separation cell and at least one determination cell are provided as discrete cell units which are independently separate from one another in a same reaction disk body. Guigan fails to teach or suggest such features. According to Guigan, when the preparation cartridge 60 and the analysis cartridge 40 are assembled to the rotor assembly 4, they are interconnected so as to communicate by way of an outlet orifice 91 provided at the bottom of the cartridge 60 (piercing member 19), and operate as a single body (see Fig. 6, col. 6, lines 29-34). This is in stark contrast to the presently claimed invention



of claim 1, in which supernatant is transferred with a pipette, since the cells are truly independent of one another (non-communicating).

With regard to the Examiner's characterization of the term "structural configuration for preventing a suspension from flowing out during centrifugal separation" as being "merely functional," applicants respectfully disagree. The term "structural configuration" in and of itself, involves no functional step. The Examiner has not explained why she considers it, *per se*, improper to describe a structure in terms of a function it performs, rather than strictly based upon its shape, by specific reference to cited legal authority. Applicants respectfully submit that one of ordinary skill in the art could readily develop suitable structure based upon the disclosure that would achieve blockage of flow out of the cells during centrifugation without undue experimentation, and therefore the claim is respectfully submitted as being fully enabled. Moreover, the rejection is not based upon indefiniteness grounds under 35 U.S.C. §112, second paragraph. Thus it is unclear on what legal basis the language is not being given patentable weight. Should the Examiner again raise this issue, the applicants respectfully request that the Examiner provide relevant authority in support of her position so that applicants can effectively respond.

In view of the above, it is respectfully submitted that claims 1, 3-8 and 13-15 particularly describe and distinctly claim elements not disclosed in the cited reference. Therefore, reconsideration of the rejections of claims 1, 3-8 and 13-15 and their allowance are respectfully requested.

Claims 9-10 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nilsson (US 5,472,671). Applicants herein respectfully traverse these rejections. It is respectfully submitted that the cited reference is deficient with regard to the following.

Independent claim 9 recites in pertinent part the following:

a cell being disposed in a disk body, said disk body presenting a horizontally disposed disk expanse and being rotatable about a centrally disposed and vertically oriented rotational axis, said cell being disposed radially outward of said rotational axis and having an interior configuration including a lower part thereof defining an insoluble matter collection zone and an upper part thereof defining a supernatant separation zone, a horizontal cross sectional area of said supernatant separation zone being greater than a corresponding cross sectional area of said insoluble matter collection zone thereby creating a shelf at a boundary between said supernatant separation zone and said insoluble matter collection zone; and

a lid being disposed at an upper part of the cell, said lid being positioned to only partially cover the cell so as to leave an opening through which the supernatant is withdrawable from above while preventing the suspension in the cell from flowing out during centrifugal separation, at least a radially outward internal wall of the cell being disposed in a substantially parallel orientation with said rotational axis about which said separation cell is eccentrically revolvable, said substantially parallel orientation being maintained during said centrifugal separation

The claim is amended to relate the claimed cell to its positioning relative to a disk body in which it is formed. The claimed invention includes a lid which is positioned to only partially cover the cell so as to leave an opening through which the supernatant is withdrawable from above while preventing the suspension in the cell from flowing out during centrifugal separation, a feature not taught or suggested by Nilsson et al..

Applicants respectfully believe that the Examiner's understanding of the invention disclosed in Nilsson et al. continues to be inaccurate, based upon her analysis in the Response to Arguments on page 16, first full paragraph of the final

Office Action. It is clear from the reference disclosure that the cuvette disclosed therein is rotated about an axis of rotation C shown in Fig. 1 and as described at column 4, lines 33-43, and which extends perpendicular to a plane of the drawing sheet. Expressed another way, the cuvette 10 “orbits about C, and shown by the curved arrow in Fig. 1. The disclosure at col. 4, lines 42-44 cited by the Examiner actually supports applicants interpretation explained above, rather than the Examiner’s. Indeed, in Fig. 1, the center of rotation C is located on the extension of the vertical line shown in the figure. Since Fig. 2 is a view rotated 90 degrees about the vertical line of Fig. 1 (note positions of 16, 18, and 22), the axis of rotation C would extend along a horizontally drawn line above the drawing, if it were to be depicted in Fig. 2. Thus, the only structure that could possibly be considered analogous to the claimed lid would be the first wall 12 which forms the uppermost structure of the cuvette, and not the hydrophobic material 20. And, as clearly described and shown, this structure (i.e., first wall 12) entirely seals the cavities 16, 18 and 22 from above. This is in stark contrast to the claimed invention in which the lid only partially covers the cell.

In view of the above, it is respectfully submitted that claims 9-10 and 12 particularly describe and distinctly claim elements not disclosed in the cited reference. Therefore, reconsideration of the rejections of claims 9-10 and 12 and their allowance are respectfully requested.

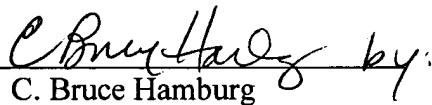
Dependent claim 16 is added and is submitted as patentable over the cited art of record based on the subject matter cited therein in addition to the subject matter of claims 9 and 10 from which it depends.

A Request for Continued Examination (RCE) is being filed concurrently herewith, in which applicants request a three (3) month extension of time for responding to the Office Action.

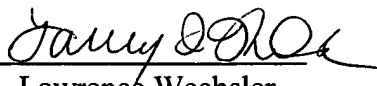
The USPTO is hereby authorized to charge any fee(s) or fee(s) deficiency or credit any excess payment to Deposit Account No. 10-1250.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,  
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enc: Replacement sheet including Fig. 4, and a Request for Continued Examination (RCE).